UtrechtLawReview

Thomas Verheyen, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) 15(1) Utrecht Law Review pp. 44–56. DOI: https://doi.org/10.36633/ulr.541

ARTICLE

Modern Theories of Product Warnings and European Product Liability Law

Thomas Verheyen*

Scholars inside and outside Europe have recently argued that product liability law should recognise the sheer complexity of designing an adequate warning. In the US, for instance, it has been suggested that a plaintiff bringing a claim based on a defective warning should be required to prove which reasonable alternative warning would have prevented her from suffering harm. While much can be said in favour of a more refined approach to product warnings, these proposals are incompatible with many key characteristics of positive European product liability law as construed by the Court of Justice of the European Union. These scholars' recommendations invite us to reconsider some of the features of European product liability law and decide upon a direction for the future.

Keywords: European product liability law; defect; warnings; product information; causation; accident prevention

1. Introduction

The legal treatment of *unhealthy* but/and *(un)lawful* products would not be the same without product liability law. Product liability law alleviates the negative effects of permitting dangerous but useful products by shifting the financial consequences of a loss from the victim of a product-related accident to the producer, who can spread it amongst all consumers. *Product information* is another essential element in the broader legal framework on dangerous products. This article is concerned with the interaction between both. In particular, it discusses the influence of product information on the liability of the producer.

This influence has never been uncontested because product information has an ambiguous nature. An upside of adequate warnings is that they make a product safer while simultaneously enhancing the possibility of the consumer to make an informed choice.[1] The downside of adequate warnings and instructions is that warnings and instructions always rely on the users to take the necessary physical steps in preventing the harm.[2] When the latter fail to take those steps in spite of a given warning the producer mostly escapes liability and the losses rest with the consumer. This specific feature of warnings and instructions could be perceived as problematic in the context of product liability law because of the tension with the foundational idea that product liability law is there to protect consumers.[3]

In recent years, scholars in Europe and beyond have urged a more nuanced approach to warnings and instructions in product liability law. In her 2012 PhD dissertation, S.B. Pape persuasively demonstrates how complicated it is to design adequate warnings and instructions.[4] She argues that a warning should be assessed based on its capacity to prompt the user to change her behaviour. Generally speaking, this means that merely passing on information does not liberate a producer from liability. However, if the producer proves the warnings were optimally designed with a view to a change in the consumer's behaviour, Pape contends that he should not be required to cover the plaintiff's loss. At the other side of the Atlantic, Twerski and Henderson – the reporters of the 1998 *Restatement Third, Torts: Products Liability* – have suggested that a plaintiff making a claim based on a defective warning should be required to prove which 'reasonable alternative warning' would have prevented the harm – putting warning claims more on a par with claims based on an allegedly defective physical design.[5]

These proposals deserve our full attention. On closer inspection, however, they seem incompatible with several key features of positive European product liability law based on the European Product Liability Directive (EPLD) as interpreted by the Court of Justice of the European Union (CJEU).[6] In this article, I will discuss these recent proposals and how they relate to positive European product liability law. The first part of the contribution will give some necessary background information on the central concepts of 'defect' and 'causation' (2). I then go on to discuss the two proposals (3) and highlight the diverse ways in which they are incompatible with positive European product liability law (4).

The main goal of this article is *descriptive*. It is meant to inform policy makers and legislators on what should be changed if they were to opt for the 'modern approach' to product warnings that is presented in this article. The last section summarily deals with the normative questions that are raised by the descriptive comparison. However, it must be noted that a full discussion of these normative questions deserves an entirely different and separate article.

In addition, the focus lies exclusively on the effect of warnings on product liability under the regime of the EPLD. This means that any post-sale duty to warn will not be discussed. As to case law, my focus lies on the jurisprudence of the CJEU. It is the CJEU which sets out the directions for European product liability law, and in the last few years this direction has become increasingly clear.

2. Background on the notion of 'defect' and 'causation' in the EPLD

Article 4 of the EPLD provides that 'the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage'. This part provides the necessary background on the notion of 'defect' and 'causal relationship' under the EPLD.

A producer only has to compensate if his product is defective. A product is defective if it is unsafe.[7] The influence of information on product liability is a sub-question of the question when a product is defective. This contribution exclusively deals with so-called 'information', 'presentation', 'warning' defects, which should be distinguished from defects in the physical design of the product (design defects)[8] or problems with one specific (batch of) products (manufacturing defects).[9]

The EPLD considers a product defective 'when it does not provide the safety which a person is entitled to expect, taking all circumstances into account (...)' (Article 6 of the EPLD). Since the definition of defect in the EPLD refers to 'the safety which a person is entitled to expect', the European test can be characterised as a 'consumer expectations test'. The consumer expectations test is based on the hypothetical obligation of the producer to make sure the product conforms with the safety expectations of consumers. The European

* PhD Researcher at Ghent University Faculty of Law and Criminology, Belgium (funded by the Special Research Fund of Ghent University). Master of Laws, Ghent University, 2015; LL.M. Yale Law School (BAEF Fellow), 2017. email: thomas.verheyen@ugent.be.

Many thanks to Conor Casey, Marc Kruithof, Matthias Van der Haegen, the editors of the book 'Ongezond en (on)geoorloofd', the participants of the workshop 'Liability and Insurance' on the Ius Commune Conference 2017 and the two anonymous reviewers for insightful comments on earlier versions of this article and/or the oral presentation of its content.

This text is an English translation and abbreviated version of a (Dutch language) book chapter entitled 'Redelijke alternatieve waarschuwingen en Europese productaansprakelijkheid' published in A.L.M. Keirse et al. (eds.), *Ongezond en (on)geoorloofd – Publiek- en Privaatrecht & legale maar gezondheidsbedreigende producten en diensten* (2018), pp. 287–312, which was written on the occasion of the same conference which this ULR Special Issue is based upon.

[1] A commonly made distinction is that between warnings and instructions. While warnings indicate (sometimes inherent) risks associated with a product, enhancing the consumer's freedom of choice, instructions indicate how to avoid the risks, and what to do if the risks materialise. Terminology can differ, however. I will use the term warning generally to refer to both. See on this issue S.B. Pape, *Warnings and Product Liability – Lessons learned from Cognitive Psychology and Ergonomics* (2012), p. 257; S. Lenze, 'German product liability law: between European Directives, American Restatements and common sense', in D. Fairgrieve (ed.), *Product liability in comparative perspective* (2005), p. 105.

[2] A. Twerski & J. Henderson, 'Fixing Failure to Warn', (2015) 90 *Indiana Law Journal*, p. 246.

[3] See T. Verheyen, 'Full Harmonization, Consumer Protection and Products Liability: a fresh reading of the case law of the ECJ', (2018) *European Review of Private Law*, pp. 119–140.

[4] Pape, supra note 1.

[5] Twerski & Henderson, supra note 2, pp. 237–256.

[6] Directive 85/374/EEC on the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, OJ L 210, 7. 8. 85, p. 29.

[7] H. Taschner, 'Product liability: basic problems in a comparative law perspective', in D. Fairgrieve (ed.), *Product liability in comparative perspective* (2005), p. 159.

[8] 'A design defect occurs where the product accords with specification but is still unreasonably dangerous' (C. Hodges, *Product Liability. European Laws and practice* (1993), p. 98).

[9] M. Reimann, 'Liability for defective products and services: emergence of a worldwide standard?', in International Academy of Comparative Law (ed.), *Convergence of legal systems in the 21st century* (2006), p. 398.

choice for a consumer expectations test was no coincidence.[10] Plaintiffs in a product liability suit face many difficulties in proving where the defect originates exactly. This explains the choice for strict product liability[11] with an emphasis on the product,[12] rather than on the reasonable or unreasonable behaviour of the producer.

The main alternative test from a comparative perspective is the risk-utility test.[13] Risk-utility balancing is a strategy commonly used in tort law to determine whether the defendant committed negligence or another tort.[14] Applied to product liability, it focuses on the risks involved in the production, marketing and use of the product, and whether the risks brought about by the product and/or its specific features are reasonable in comparison to its expected utility.[15]

It is important to realise that the question of defectiveness has a much more limited scope in a typical case than the previous paragraphs could suggest. Plaintiffs cannot merely prove that the product was unsafe *in general*. What they have to prove is that *this particular defect in this particular product* caused *their harm*. What the plaintiff is required to prove is specific in two ways. These two ways of specificity are both linked to the need to prove a (but-for) causal link between the defect and the harm. First, not every defect of the product is a basis for compensation. Let's say Jane's harm was caused by characteristic X of product A. Unfortunately, she is only able to prove that the product was unsafe and defective because of Y and Z. Even if Y and Z are sufficient reasons for an outright prohibition of product A, Jane will not succeed in court, because she cannot prove that these identified defects caused *her harm*. Thus, from the point of view of a plaintiff making a product liability claim, the questions of *defectiveness* and *causation* are very much intertwined. The only relevant defect for her is the one that caused her harm, if any. Secondly, every proof of but-for causation presupposes the proof that the individual product that purportedly caused the plaintiff's harm was also affected by the product's *in abstracto* defect.[16] This is a second way in which the proof of causation is linked to the proof of general defectiveness of the product, and both are important to understand what follows.

3. A modern approach to product warnings?

Scholars both in the US and in Europe have recently advocated a more nuanced approach to product warnings. Pape, Twerski and Henderson voice concerns that the current treatment of warnings and instructions does not correspond with a modern understanding of the complexity of drafting an adequate warning. They also both take an original stance about the relation between warnings and other decisions pertaining to product design and safety. This part of the contribution provides a summary of their proposals. The next section investigates how these proposals would fit under European product liability law.

3.1. S.B. Pape: Safety oriented warning requirements

Warnings and Product Liability – Lessons learned from Cognitive Psychology and Ergonomics combines insights from cognitive psychology, ergonomics and law in order to understand and improve the treatment of warnings under European product liability law.[17] Its premise is that product liability aims at prevention.[18] This is why the author, S.B. Pape, describes the term 'warning' very broadly: 'a product warning is a safety communication; it is intended to provide relevant information about the product so that undesirable consequences

[10] D. Fairgrieve et al., 'The Product Liability Directive: Time to get Soft?', (2013) 4 Journal of European Tort Law, DOI 10.1515/jetl-2013-0001, p. 7; F. Werro et al., *The boundaries of strict liability in European tort law* (2004), p. 438; H. Taschner, *Produkthaftung: Richtlinie des Rates vom 25. Juli 1985 zur Angleichung der Rechts- und Verwaltungsvorschriften der Mitgliedstaaten über die Haftung für fehlerhafte Produkte (85/374/EWG)* (1986), pp. 66–67.

[11] Case C-300/95, *Commission v United Kingdom*, ECLI:EU:C:1997:255, para. 24.

[12] D. Wuyts, 'Productaansprakelijkheid: een Richtlijn voor (n)iets?', (2008) *Tijdschrift voor Belgisch Burgerlijk Recht*, p. 12. See also the second recital to the EPLD: 'whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production'.

[13] See generally: L. Bergkamp, 'Is There a Defect in the European Court's Defect Test? Musings about Acceptable Risk', (2015) 6 *European Journal of Risk Regulation*, pp. 313–314; Reimann, supra note 9, pp. 394–397; Hodges, supra note 8, pp. 95–98.

[14] G. Howells, 'Information and Product Liability – A Game of Russian Roulette?', in G. Howells et al. (eds.), *Information Rights and Obligations: A Challenge for Party Autonomy and Transactional Fairness* (2004), p. 156.

[15] There is much discussion on the exact way in which this test should be filled in. See D. Owen, 'Toward a Proper Test for Design Defectiveness: "Micro-Balancing" Costs and Benefits', (1996–1997) 75 *Texas Law Review*, pp. 1661–1698.

[16] Except in case of a manufacturing defect, which this article is not concerned with.

[17] Cognitive psychology 'studies cognitive processes of the human mind, such as perception, understanding, thought, memory and decision making', whereas ergonomics 'deals with the interaction between people and machines' (Pape, supra note 1, p. 4).

[18] Ibid., p. 6.

can be avoided or minimized'.[19] Her work ends with a refined set of useful guidelines and recommendations about how these safety communications should be treated under European product liability law, backed-up by empirical research.

Pape considers the European liability regime for product warnings problematic in many respects. Traditionally, Pape notes, warnings have been judged based on their capacity to *inform*.[20] This is related to the above-mentioned choice-improving effect of product information.[21] As already indicated, however, key to her theory is that warnings should be evaluated against their safety-improving effect. From the perspective of prevention mere comprehension is insufficient. Comprehension is only one of many necessary conditions for a warning to lead to safer behaviour. This is why she argues that warnings should not be judged based on their capacity to convey information, but on their capacity to persuade the user into behaving more safely with regard to the product.[22]

The book demonstrates at length that the factors that determine the optimal design of a warning are manifold and conflicting.[23] Conversely, in European product liability law, the cost of designing an adequate warning is often underestimated. This underestimation motivates parties and courts to prefer basing their claim or judgment on defective warnings rather than on features of design. This tendency is exacerbated by the reluctance of judges to 'second-guess' the issues related to the physical design of a product, because they too are put off by the technicality of such assessments, which is considered higher than under a warning claim.[24]

Pape responds with a sophisticated alternative legal regime for product warnings under the EPLD. A key element in her theory is that warnings are only 'last-resort precautionary measures'.[25] The safety-increasing effect of warnings depends on the intervention of the user of the product, which cannot be taken for granted. People only act upon warnings after a substantial number of cognitive steps.[26] This is why a warning is only acceptable as a safety-increasing measure if the hazard cannot be 'designed out' (the first option to consider) or 'guarded against' (the second option).[27] The background insight is that warnings are part of one and the same overall exercise of product design.[28] Combining these different elements, Pape advances a new type of warning defect. She distinguishes the 'misuse of a warning' from the traditional 'absence of a warning' and 'inadequacy of a given warning'. A warning is misused if the appropriate hierarchy of risk-prevention (design out – guard against – warn against) is not followed.[29] Whether a warning has been misused should be determined following a risk-utility analysis considering costs and benefits of alternative design solutions.[30]

Once a warning has been identified as the most suitable means of prevention, the question becomes whether the warning has been adequately designed taking into account the 'lessons learned from cognitive psychology and ergonomics'. If a warning is adequately designed, the producer should be exempt from liability:

> If it can be expected that there are no (substantial) safety utility/benefits or if the costs of providing the warning can be considered to outweigh the benefits attached to providing a warning, European product liability should not require the presence of a warning under the defectiveness test.[31]

As such, there should be no warning requirement for risks with an insignificant size, risks that 'arise from unreasonably expected use', risks that are 'obvious' or 'generally known' or risks that were 'undiscoverable at

[19] Ibid., p. 256.

[20] Ibid., p. 342. Hodges, supra note 8, pp. 108–109. See as an example the American *Restatement Second: Torts*, §402A, comment j: 'Where a warning is given, the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in defective condition, nor is it unreasonably dangerous.'

[21] Pape, supra note 1, pp. 359–360.

[22] Ibid., p. 277.

[23] Ibid., p. 297.

[24] Ibid., p. 342.

[25] Ibid., p. 323.

[26] Ibid., pp. 325–326.

[27] Ibid., p. 327.

[28] Ibid., pp. 336 et seq.

[29] Ibid., p. 339.

[30] Ibid., pp. 343–346.

[31] Ibid., p. 296.

the time of putting the product into circulation'.[32] Sometimes a warning is not only redundant, but plainly dangerous. Unnecessary warnings divert the attention from more important hazards, or numb the public with regard to future warnings that at one point might be essential to avoid imminent dangers.[33] Because drafting an adequate warning is so hard, she also recommends to test the warning's design before it is adopted (on the condition it is not too burdensome).[34]

There are two sides to her analysis. On the one hand, she urges us to acknowledge that warnings are 'no safety panaceas'.[35] This insight increases the pressure on producers to opt for alternative physical design solutions rather than using a warning to swiftly and summarily get rid of the risk of liability. As such, her analysis provides a theoretically sounder version of the proposals of a few European scholars to deny legal effect to overly general warnings based on the prohibition of exoneration clauses in Article 12 of the EPLD.[36] On the other hand, shallow 'absence of warning claims' with regard to an insignificant risk will no longer be of much avail for plaintiffs if added warnings are unwarranted from the point of view of harm prevention. Moreover, producers that can prove that the warning was tested in advance will have a strong argument against such claims. This raises questions about the compatibility with European product liability law as currently construed by the CJEU.

3.2. Twerski and Henderson: reasonable alternative warnings

Aaron Twerski and James Henderson are best known as the reporters of the 1998 *Restatement Third, Torts: Product Liability*. This restatement supplanted the consumer expectations test of paragraph 402A of the *Restatement Second, Torts* with a risk-utility test for design and warning defects.

The test in the restatement is worded as follows:

> A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:
>
> (a) contains a *manufacturing defect* when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
>
> (b) is *defective in design* when the *foreseeable risks of harm* posed by the product could have been reduced or avoided by the adoption of a *reasonable alternative design* by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission, of the alternative design renders the product *not reasonably safe*;
>
> (c) is *defective because of inadequate instructions or warnings* when the *foreseeable risks of harm* posed by the product could have been reduced or avoided by the provision of *reasonable instructions or warnings* by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product *not reasonably safe*.[37]

This focus on foreseeability and reasonableness marks the shift away from the consumer expectations test towards a risk-utility test embodying elements of negligence law – at least regarding design and warning defects.[38] That said, the attentive reader will have noticed that while subparagraph (b) mentions the 'reasonable *alternative* design' (emphasis added) subparagraph (c) does not. This difference is explained in comment i:

> The defectiveness concept is more difficult to apply in the warnings context (...) product warnings and instructions can rarely communicate all potentially relevant information, and the ability of a plaintiff to imagine a hypothetical better warning in the aftermath of an accident does not establish that the warning actually accompanying the product was inadequate.[39]

[32] Ibid., p. 293.
[33] Ibid., pp. 383–385.
[34] Ibid, p. 390.
[35] Ibid., p. 325.
[36] Howells, supra note 14, p. 164; Taschner, supra note 10, pp. 146–147.
[37] Restatement Third, Torts: Products Liability, § 2 (emphasis added).
[38] Supra, section 2.
[39] Restatement Third, supra note 37, comment i.

Note the stark contrast with the comments on design defect: 'Under prevailing rules concerning allocation of burden of proof, the plaintiff must prove that such a reasonable alternative was, or reasonably could have been, available at the time of sale or distribution.'[40] In short, there is no requirement for the plaintiff bringing a warning claim to prove which reasonable alternative warning would have prevented the harm, whereas there is in the case of design defects.

This difference is the starting point of Twerski and Henderson's clear and concise *Fixing Failure to Warn*.[41] In this article they admit they made a mistake by omitting such a requirement in the *Restatement Third*. Like Pape, they argue that warning and design issues have more in common than earlier assumed and that these commonalities should be reflected in the elements the plaintiff is required to prove. Warning and design claims share the building blocks of the 'untaken precaution' on the one hand and 'actual causation' on the other.[42] As to the *untaken precaution*, or what they call 'general causation' a plaintiff must prove that an alternative design (including safety communications) would have made the product safer. This is the proof of the *defect* in the product. *Actual causation* means that the plaintiff must demonstrate that *this defect* consisting in the omission of a reasonable alternative design and/or warning has caused her individual harm.[43]

Formulated differently, Twerski and Henderson want to align design and warning claims by demanding that a plaintiff bringing a claim based on a defective warning offers a reasonable alternative warning (RAW) for the court to consider:

> Without a RAW requirement, the plaintiff is more likely to be able to have it both ways – to play up the need for a more forceful warning in the abstract while playing down or ignoring altogether the sorts of real-life costs, monetary and nonmonetary, that requiring more forceful warnings would generate. (...) Not only would a RAW help to highlight the costs associated with a better warning, but a RAW would also help to reveal any weaknesses in the plaintiff's claim of but-for causation.[44]

This last point on causation reflects the intimate relationship between defectiveness and causation discussed above.[45]

Twerski and Henderson acknowledge the singularity of warnings as measures of harm-prevention. Warnings always presuppose cooperation of a 'risk manager' acting upon the warning: the user, a parent, etc. This is why, they too, think that an alternative physical design should be preferred over a warning as a safety measure,[46] and why the authors favour the adoption of a 'heeding presumption' – putting the burden on the producer to prove that the addressee of a warning would not have cooperated, rather than putting the burden on the plaintiff to prove the contrary.

3.3. Both contributions complement each other

Explicitly comparing both approaches reveals a different motivation but conclusions that generally complement each other. Pape wishes to improve safety and values answering empirical questions empirically rather than based on imprecise lawyerly assumptions. Twerski and Henderson, on the contrary, seem not all too bothered by a lack of empirical rigour. Against the background of Pape's dissertation, it could even be argued that they underestimate the complexity of designing an adequate warning.[47] What they do decry is the lack of analytical precision adopted by the courts, leading to a high number of unwarranted claims based on insufficient proof of causation.[48]

Nevertheless, both approaches have a lot in common. They share the insight, for instance, that design and warning issues cannot sensibly be separated.[49] Because the effect of warnings necessarily depends on their

[40] Ibid., comment d.
[41] Twerski & Henderson, supra note 2.
[42] Ibid., pp. 240–242.
[43] Ibid., pp. 241–242.
[44] Ibid., p. 244. For examples of how this requirement of causation is neglected, ibid., pp. 248 et seq.
[45] Supra, section 2.
[46] Twerski & Henderson, supra note 2, p. 246.
[47] 'We do not pretend that drafting warnings is an easy task, (...). But the difficulties should not be overstated. In many cases, plaintiffs will be able to construct RAWs that are sufficiently credible so that a fact finder may conclude that the failures to warn caused the injuries suffered by the plaintiffs.' (Ibid., p. 255).
[48] This concern about causation is also voiced by the producer lobby in Europe, as reflected in the quinquennial reports by the European Commission. See for instance COM(2006) 496 final, p. 9.
[49] Twerski & Henderson, supra note 2, p. 246; Pape, supra note 1, pp. 336 et seq.

being followed, this observation leads both of them to conclude that changes in design should be preferred over the use of warnings, which have to be treated as 'last-resort precautionary measures'.[50] As Pape puts it, 'it is easier to redesign products than to redesign the behaviour of consumers'.[51] This seems congruent with the foundational idea of asymmetry between producer and consumer that lies at the basis of product liability.[52]

In addition, Pape's dissertation carries elements reflecting the central tenet of Twerski and Henderson's piece – a RAW requirement. The RAW requirement that Twerski and Henderson advocate is analytically necessary for the proof of causation central to every tort case. You cannot prove that the defective state of the product caused your harm if you do not propose an alternative design which would have prevented your harm. While causation as such falls outside the scope of Pape's dissertation,[53] the issue pops up in her discussion of the factors relevant to determine whether a warning was adequate. Among those elements, she lists 'factors associated with an alternative design of the warning.'[54] Pape concedes that the EPLD does not impose a RAW requirement, but 'believe[s] that this component is closely linked with answering the question why a warning is considered inadequate'.[55] Arguably, this is because of the link with causation.

The finding that design and warnings are linked, that warnings should count as 'last-resort precautionary measures' and that plaintiffs should provide courts with reasonable alternative warnings are all elements indicating the risk-utility approach underlying both theories. Of course, Twerski and Henderson are merely being faithful to their previous work shaping product liability law in the US. Their piece is only a postscript to earlier arguments based on their evolved understanding of warning defects. Pape's unequivocal endorsement of risk-utility elements, conversely, is more surprising considering the centrality of the consumer expectations test in European product liability theory.

4. Meanwhile, inside the European courts

Unfortunately, the proposals of Pape, Twerski and Henderson do not fit easily into this part of European law. Some of the nagging points are superficial, others doctrinal and theoretical; some follow from the wording of the directive, while others emanate from the case law of the CJEU. The pressing question appears to be whether European product liability law is ready to accept theoretical refinement against the price of losing the ability to easily compensate victims of an accident with a product allegedly containing a warning defect.

4.1. Warnings as passe-partout

A first tension between the proposals of Pape, Henderson and Twerski and European product liability law lies in the way in which parties in a product liability suit and the courts generally deal with warning claims. Information defects are frequently used as an elegant way to avoid technical discussions on physical product design.[56] This comes in handy for plaintiffs, who generally have no or less knowledge on these subjects.[57] As Pape mentions herself, judges are reluctant to 'second-guess' these design decisions.[58]

One good illustration of this tendency is the evolution of the discussion of warning requirements for 'generally known risks' in European scholarship on product information. Traditionally, there has been no warning requirement for generally known risks.[59] In the 1990s, people began to note an inclination to equally require warnings for these risks.[60] In 2014, Micklitz wrote without much further discussion that producers are required to warn for all foreseeable risks.[61]

Apart from this understandable disinclination to second-guess technical questions, judges also tend to be oblivious to the full extent of the causation requirement. Twerski and Henderson provide a few examples from the American context in their piece.[62] However, the phenomenon is also present in European jurisdictions.[63] This will be discussed below, in the section on burden of proof.

4.2. Consumer expectations, not risk-utility

Another objection against Pape, Twerski and Henderson's recommendations from the point of view of European product liability law is the consumer expectations test from Article 6 of the EPLD: 'A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account (…).' As we have seen, the European legislature preferred a (strict) consumer expectations test over risk-utility balancing because it fitted better with its ambition to solve the 'problem of increasing technicality'.[64]

The liability for manufacturing defects is undeniably strict, also in Europe.[65] Moreover, many commentaries on defectiveness in European product liability law assume that we in fact have a consumer expectations test. In a recent book, for instance, Machnikowski has wondered whether the 'tendency to examine whether those expectations are rational using the production cost criterion – which means introducing a cost/utility analysis in the notion of defect' is 'compliant with the directive.'[66] The third report of the European Commission asks whether 'it is appropriate for a court to undertake a risk/benefit analysis when assessing what a person is entitled to expect'.[67] Advocate General Bobek explicitly dismissed the use of risk-utility balancing in an opinion regarding a recent case before the CJEU.[68]

Howells proposes a standard that is stricter than reasonableness. His formulation of the consumer expectations test is based on the actual expectations of the individual consumers. Under his reading of the test a producer only escapes liability if the consumer knows, based on the information provided with the product, that she will be the one that is struck by the hazard.[69] His example is aspirin. Aspirin inevitably causes internal bleeding in some of its users, but it is not clear in whom exactly. Howells thinks the producer should compensate the victim even if the safety notice mentions the slight chance of internal bleeding because:

> aspirin, when it causes a user to bleed, does not provide the safety expected, because the user did not expect it to harm him (…) if strict liability is to mean something different from negligence such cases are candidates for liability.[70]

Machnikowski, Bobek and Howells are arguing against those that consider a risk-utility analysis inevitable if it comes to product warnings, even under the European consumer expectations test. These scholars make the descriptive point that it is well-nigh impossible to think of anything else than foreseeable risks and reasonable preventive measures when assessing the adequacy of product information.[71] Even the intellectual

[50] Twerski & Henderson, ibid.; Pape, ibid., p. 323.

[51] Twerski & Henderson, ibid., p. 247.

[52] Supra, introduction.

[53] Pape, supra note 1, p. 10.

[54] Ibid., p. 370.

[55] The difference between her account of the role of RAWs and that of Twerski and Henderson again being that she thinks plaintiffs will generally be better equipped if they try to formulate a reasonable alternative warning in their claim (ibid., p. 370). Conversely, Twerski and Henderson believe that this will make claims harder to prove (Twerski & Henderson, supra note 2, p. 246: 'Quite simply, proof of a RAW would allow the tribunal to compare the specifics of the RAW against the specifics of the actual marketing of the defendant's product, instead of trying to intuit its way to a conclusion regarding specific causation based on vague allegations that some sort of unspecified warnings would have actually prevented the plaintiff's harm').

[56] See recently <http://www.bbc.co.uk/news/health-41399848> (last vistited 19 September 2019), on the drug Epilim and its side effects if taken during pregnancy.

[57] Pape, supra note 1, p. 342; Hodges, supra note 8, p. 99.

[58] Pape, supra note 1, p. 342.

[59] Lenze, supra note 1, pp. 105 and 114; Howells, supra note 14, p. 158; Hodges, supra note 8, p. 107; See also Restatement Second: Torts, §402A, comment j: 'But a seller is not required to warn with respect to products, or ingredients in them, which are only dangerous, or potentially so, when consumed in excessive quantity, or over a long period of time, when the danger, or potentiality of danger, is generally known and recognized. Again the dangers of alcoholic beverages are an example, as are also those of foods containing such substances as saturated fats, which may over a period of time have a deleterious effect upon the human heart.'

[60] H. Cousy, 'Exoneratieclausules en alternatieve beschermingsconstructies in de wet produktenaansprakelijkheid', in J. Herbots (ed.), *Exoneratiebedingen* (1993), p. 63.

[61] H. Micklitz, 'Liability for defective products and services', in N. Reich et al. (eds.), *European Consumer Law* (2014), p. 248. See also ambiguously: D. Fairgrieve et al., 'Product Liability Directive', in P. Machinkowski (ed.), *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies* (2016), pp. 56–58, in which the authors note on the one hand that for inherently dangerous products 'information about *any* possible risk is essential to the safety assessment', while at the same time quoting the product safety directive, which mentions 'risks [that] are not immediately obvious without adequate warnings'.

[62] Twerski & Henderson, supra note 2, pp. 248–251.

[63] See, e.g., Rb. Brussel 10 februari 2005, *JLMB* 2006, 1193.

[64] Fairgrieve et al., supra note 10, p. 7; Werro et al., supra note 10, p. 438; Taschner, supra note 10, pp. 66–67.

[65] H. Taschner, 'Produkthaftung – Noch einmal: Verschuldenshaftung oder vom Verschulden unabhängige Haftung?', (2012) *Zeitschrift für Europäisches Privatrecht*, p. 562; H. Bocken, 'Buitencontractuele aansprakelijkheid voor gebrekkige producten', in H. Bocken, C. Cauffman *et al.*, *Bijzondere overeenkomsten* (2008), p. 367; S. Lenze, supra note 4, p. 108.

[66] P. Machnikowski, '*Conclusions*', in P. Machnikowski (ed.), *European Product Liability – An Analysis of the State of the Art in the Era of New Technologies* (2016), p. 695.

[67] COM(2006) 496 final.

[68] Opinion Bobek concerning Case C-621/15, *N.W, L.W & C.W v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine & Carpimko*, ECLI:EU:C:2017:176, para. 87.

[69] Howells, supra note 14, p. 160.

[70] Ibid., p. 163.

[71] Pape, supra note 1, p. 45; Wuyts, supra note 12, p. 14.

father of the directive concedes that cases of information defects can satisfactorily be dealt with under a fault regime as well.[72] The ambiguity is also present in paragraph 402A of the *Restatement Second: Torts*, the origin of the European consumer expectations test. Its comment j on 'directions or warning' states that if a hazard is not generally known 'the seller is required to give warning against it, if he has knowledge, or by the application of reasonable, developed human skill and foresight should have knowledge, of the presence of the ingredient and the danger'[73] – a classic description of the negligence standard.

In other words, Pape, Twerski, and Henderson are endorsing a position attacked by some, and considered an inevitable truth by others. As such, they take the underdog position in a complex debate central to European product liability theory.

4.3. The low burden of proof in European product liability law

The theories of Pape, Henderson and Twerski considerably complicate the task of parties and judges in a product liability dispute. Under the proposed regimes it will not be possible any more to process such cases without much further ado by pointing at the presence or absence of warnings indicating the risk that materialised.[74] However, the tendency of summarily dealing with complicated issues of design and causation is implicitly endorsed by the case law of the CJEU on the burden of proof in product liability law. In the last few years, the focus of the CJEU has shifted from enforcing the fully harmonising character of the EPLD[75] to reducing the burden of proof of the plaintiff in a product liability dispute.[76] Although there have been no cases which directly relate to warning claims,[77] the trend in the case law of the CJEU is sufficiently clear.

From its very inception product liability law has largely revolved around issues of proof. The history of product liability law is one of coping with asymmetries between manufacturers and their consumers by optimally lowering the burden of proof for the victim in a product related accident. This is exactly the reason why the – supposedly – strict liability test of Article 6 of the EPLD was adopted. The test of Article 6 functions as a typical contractual *obligation de résultat* for producers. It suffices for the plaintiff to point at the product not meeting certain standards – ambiguously expressed in 'consumer expectations' – regardless of how this substandard quality came about. No proof of negligence is needed.

The strict consumer expectations test was considered a major step towards victim protection. Against this background, the European Economic Community wanted to re-emphasise its commitment to the ancient maxim '*actori incumbit probatio*' (the burden of proof rests with the plaintiff). Article 4 was inserted in the EPLD, which provides that 'the injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage'. This was deemed necessary because many Member States had lowered the burden of proof for the victim in the years before the directive was adopted.[78]

Despite allegiance to this age-old division of labour in the courtroom, the discussion on the burden of proof never really ceased.[79] The CJEU has had occasion to rule on proof-related issues quite a few times in recent years. One thing that surprises in every such instance is its willingness to condone or outright ratify endeavours by Member States to further reduce the burden of proof of the plaintiff.

One of those cases is *Novo Nordisk Pharma*.[80] It addressed the question whether Germany could amend the special liability regime for pharmaceuticals by adding a right of the victim to obtain information about the product from the pharmaceutical company. The special liability regime for pharmaceuticals was adopted before the ELPD and as such fell under the protection of Article 13 of the EPLD. The amendment at issue was made afterwards. The CJEU ruled that the right to information fell outside the scope of harmonisation. Moreover, as 'such national legislation is only intended to eliminate the significant imbalance which exists between [producer and consumer] as regards access to information relating to that product', and as it did

[72] Taschner, supra note 10, p. 74.

[73] Restatement Second: Torts, §402A, comment j.

[74] Supra, section 3.

[75] Case C-183/00, *María Victoria González Sánchez v Medicina Asturiana*, ECLI:EU:C:2002:255; Case C-52/00, *Commission v France*, ECLI:EU:C:2002:252; Case C-154/00, *Commission v Greece*, ECLI:EU:C:2002:254; Case C-402/03, *Skov Æg v Bilka Lavprisvarehus A/S* and *Bilka Lavprisvarehus A/S v Jette Mikkelsen & Michael Due Nielsen*, ECLI:EU:C:2006:6; Case C-127/04, *Declan O'Byrne v Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*, ECLI:EU:C:2006:93; Case C-358/08, *Aventis Pasteur v O'Byrne*, ECLI:EU:C:2009:744.

[76] For a more elaborate account of this issue, see Verheyen, supra note 3.

[77] Last checked 12 June 2019.

[78] Taschner, supra note 10, pp. 59–60.

[79] As is reflected in the reports of the commission: COM(2000) 893 final, pp. 13–16; COM(2006) 496 final, p. 9; COM(2011) 574 final, p. 7.

[80] Case C-310/13, *Novo Nordisk Pharma GmbH v* S., ECLI:EU:C:2014:2385.

not reverse the burden of proof between plaintiff and defendant, the CJEU gladly approved of the right of information. The court did not just address the acceptability of a right to information under a special liability regime, but also whether such a right was admissible under the regime of the EPLD generally.

Central to the theory of Twerski and Henderson is the requirement of 'specific causation'. They insist that without a RAW requirement the actual causal link between the defect in the product and the damage sustained by the plaintiff is likely to be disregarded as a condition for liability. In *Boston Scientific Medizintechnik*,[81] however, the CJEU considerably reduced the burden of proof of the plaintiff with regard to this requirement of 'specific causation'. In this case, a producer of pacemakers and cardioverter defibrillators had advised its treating physicians to replace or alter a series of already implanted devices because some component parts might malfunction or disintegrate. Some health insurance companies tried to recover the expenses related to the surgery from the producer based on the EPLD. Because surgeons had removed and thrown away the devices, however, the insurers could not prove whether the specific product implanted in their insured's body had been defective. The question submitted to the CJEU was whether a defect in an individual product could be considered proven if it was proven instead that the product belonged to *a group of products* which have a 'significantly increased risk of failure (…)'. Thus, the question submitted to the CJEU was whether a product can be considered 'defective if pacemakers in the same product group have a significantly increased risk of failure (…), but a defect has not been detected in the device which has been implanted in the specific case (…)'. The court answered this question in the affirmative:

> where it is found that such products belonging to the same group or forming part of the same production series have *a potential defect*, it is possible to classify as defective all the products in that group or series, without there being any need to show that the product in question is defective.[82]

In one sweep, the CJEU not only refined the definition of 'defect' but also partially removed the requirement to prove causation. As we saw in section 2, full proof of causation would not only require proof of the general defective condition of the product as a type (the group of products), but also the proof of defect in the individual product that purportedly caused the harm to the plaintiff. In *Boston Scientific Medizintechnik*, the court acquiesced in a proof of the defectiveness of the product as a type only, without further requirements as to the individual product. The question remains, of course, whether the judgment in this very specific case can be extrapolated to other factual circumstances and other types of damage than replacement surgery.[83] It is possible that pharmaceuticals, or even pacemakers, have to meet higher safety standards than wallets or paper boxes. All in all, however, the *dictum* does not suggest a wish of the court to confine its ruling to this specific situation and as such the case fits well into a trend to reduce the burden of proof for the plaintiff.

The burden of proof was also the subject of the recent *Sanofi Pasteur* case.[84] In this case, the CJEU was asked to assess a French rule of evidence law that allows plaintiffs in a product liability suit relating to pharmaceutical products to prove defect and causal link based on serious, specific and consistent presumptions. The plaintiff contended that a hepatitis B vaccine produced by *Sanofi Pasteur* caused his multiple sclerosis. The proof he offered to the court ruling on the merits was the very short time-span between him taking the vaccine and the occurrence of the disease on the one hand and lack of family history of the disease on the other. While these two elements were utterly insufficient from a scientific point of view, the CJEU ratified the very lenient French rule under which these facts could suffice as a basis for serious, specific and consistent presumptions. It only puts three limits to the freedom of Member States to regulate the burden of proof. First, national evidentiary rules cannot reverse the burden of proof – as this would go against the express provision of Article 4 of the EPLD. Secondly, it cannot install 'automatic' presumptions, i.e. presumptions that force a court to consider elements as proven without it having to consider the other evidence provided. Thirdly, Member States cannot require scientific proof of the causal link. Considering the facts of the case, it is the third judgment in a row in which the CJEU has ruled in favour of the plaintiff-victim in proof related matters.

[81] Case C-503/13, *Boston Scientific Medizintechnik GmbH v AOK Sachsen-Anhalt — Die Gesundheitskasse (C-503/13) & Betriebskrankenkasse RWE (C-504/13)*, ECLI:EU:C:2015:148.

[82] Ibid., para. 41.

[83] B. Van Leeuwen & P. Verbruggen, 'Resuscitating EU Product Liability Law? Contemplating the Effects of Boston Scientific Medizintechnik GmbH v. AOK Sachsen-Anhalt and Betriebskrankenkasse RWE (Joined Cases C-503/13 and C/504/13)', (2015) *European Review of Private Law*, pp. 908–910; Bergkamp, supra note 13, pp. 317–318.

[84] Case C-621/15, *N.W, L.W & C.W v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine & Carpimko*, ECLI:EU:C:2017:484.

To recap, the CJEU is a trend setter in facilitating proof of the elements listed in Article 4 of the EPLD. Although the CJEU has not had the occasion to rule on these issues in relation to warning claims, the trend in its case law is clear enough to provide a legal counterargument against the 'modern' regime for warning claims spelled out in previous section of this article. The underlying policy question which is reflected in the different take on proof by the CJEU on the one hand and Pape, Twerski and Henderson on the other will be discussed under the next heading.

4.4. Indifference or partiality – prevention or compensation

The case law is not only plaintiff-friendly with respect to the burden of proof. Some matters are clearly settled by the directive, but as soon as there is room for interpretation the CJEU takes a victim-friendly stance. No exceptions are allowed to the rule that a 500 EUR threshold/deductible applies for damage to property (Article 9 of the EPLD), or the fact that suppliers are only liable if no EU-producer or importer can be identified (Article 3 of the EPLD). Member States that keep in force provisions more favourable to victims have been rebuked by the CJEU.[85] That said, the CJEU has interpreted the directive in a manner which frequently favours the consumer-victim. One of the ways in which it does this is by restrictively interpreting the scope of harmonisation. This happened for instance in *CHU Besançon*, in which the court gave green light to a French liability provision very similar to the regime of the EPLD holding service providers liable that used defective products they did not manufacture.[86] In the *Novo Nordisk Pharma* case discussed above, the court ruled that provisions giving a right to information to the plaintiff fell outside the scope of the directive.[87] Other examples of this readiness are the strict interpretation of grounds for exemption in Article 7 of the EPLD,[88] and the abovementioned cases on the burden of proof, in which the court consistently simplifies the task of plaintiffs.

This should not surprise, as the overall equilibrium drawn by the EPLD is favourable to consumers. This is clear from the preamble, in which most provisions are said to be inspired by consumer protection.[89] Another argument for this position is that exemption clauses are only prohibited in the relationship between producer and injured person (Article 12 of the EPLD). This reflects the principle, as expressed in the *Sanofi Pasteur* case, that the producer should compensate if its product causes damage.[90]

The specific conception of consumer protection embodied by the EPLD is the protection of consumer-victims through compensation. This is clear from the elements discussed above, which reflect the focus of the EPLD on compensation, rather than other rationales such as prevention, efficiency or procedural equality.[91] In practice, this benefits the consumer-victims and impairs the interests, not only of producers but also of consumers as a class. In a market without price regulation, the increased financial burden on the producers because of the increased liability leads to higher prices, which means that the bottom end of the consumer body is prevented from buying the products. Safer products are thus preferred over cheap products. Consumers who would have bought the product under a less victim-oriented liability regime suffer a welfare loss. Sometimes, this can lead to inefficient price increases.[92]

The bottom line of Twerski, Henderson and Pape's position is that we should focus on warnings that genuinely make a difference in safety. Twerski and Henderson approach this from the angle of but-for causation. In their vision, a producer should only be forced to compensate based on a warning defect if a reasonable alternative warning, as identified by the plaintiff, would actually have made a difference in safety. Pape's ultimate standard for the adequacy of warnings – and thus not for causation but for defectiveness – is the *ex ante* safety-improvement of warnings, which sometimes entails not warning for one hazard if it is outweighed by another one.

[85] Case C-183/00, *María Victoria González Sánchez v Medicina Asturiana*, supra note 75; Case C-52/00, *Commission v France*, supra note 75; Case C-154/00, *Commission v Greece*, supra note 75.

[86] Case C-495/10, *Centre hospitalier universitaire de Besançon v Thomas Dutrueux & Caisse primaire d'assurance maladie du Jura*, ECLI:EU:C:2011:869.

[87] Case 310/13, *Novo Nordisk Pharma GmbH v* S, ECLI:EU:C:2014:2385.

[88] Case C-203/99, *Henning Veedfald v Århus Amtskommune*, ECLI:EU:C:2001:258; Case C-127/04, *Declan O'Byrne v Sanofi Pasteur MSD Ltd & Sanofi Pasteur SA*, supra note 75.

[89] See recital 4, 5, 6, 8, 9, 10, 12, 16 and 17.

[90] Case C-621/15, *N.W, L.W & C.W v Sanofi Pasteur MSD SNC, Caisse primaire d'assurance maladie des Hauts-de-Seine & Carpimko*, supra note 84, para. 31.

[91] The focus of European product liability law on compensation is also noted by Pape (supra note 1, p. 6).

[92] This trade-off is discussed by A. Polinsky & S. Shavell, 'The Uneasy Case for Product Liability', (2010) 123 *Harvard Law Review*, p. 1472. Of course, the choice for safer rather than cheaper products is one that is implicit in other policy decisions as well.

In the context of product liability, aiming for prevention is very reasonable.[93] Unlike torts that cover certain intentional inflictions of harm or even the general tort of negligence, product liability *par excellence* should be judged against its aggregate effects because it deals with aggregate and not individualized risks. In the context of product warnings, the tendency to alleviate the burden of proof of the plaintiff, and thus to prefer the consumer-victims over the consumers as a class, is not without risk. Pape shows that a wide interpretation of the risk covered by product liability can have adverse effects on overall safety. Holding a producer liable without figuring out first whether an added warning would have made the product safer incentivises the producer to 'overwarn', which Pape well demonstrates has adverse safety effects.[94]

Nevertheless, introducing a risk-utility regime as a solution would create a new cause of concern. The risk-utility test is fundamentally indifferent as to whom will bear the loss after a product-related accident. Even in an interpretation of the test that focuses on safety rather than *overall* cost-reduction, the test is unconcerned with favouring either the plaintiff or the defendant in a product liability suit, as long as the adopted rule leads to overall efficiency or optimal safety.[95] The point of view of risk-utility balancing is not that of the individual parties in the dispute, but of the systemic effects of the liability regime.[96] Thus, the introduction of an unmitigated risk-utility regime would entail a negation of the idea that product liability law is meant to protect the weaker party, be it the individual consumer-victim, or consumers as a class. Confronting this concern would require a profound reconceptualisation of product liability law, which falls outside of the scope of this article.

5. Conclusion

The proposals of Pape, Twerski and Henderson are straightforward. They have a well-defined motivation and are oriented towards improving product liability law in line with that spirit. Pape urges us to consider the benefits of a preventive treatment of product liability. Twerski and Henderson want to reemphasise the classic condition of causation to reduce the number of unwarranted claims. Upon further reflection, however, they seem to be swimming against the European current. The majority view considers the EPLD an instrument for compensation. This is illustrated by the consumer expectations test and the low burden of proof for the plaintiff. Pape, Twerski and Henderson seem to look at the problem from the point of view of *ex ante* optimisation of (safety) risks and benefits and from the point of view of theoretical simplicity.

Yet making the regime more stringent towards plaintiffs by introducing a risk-utility regime and increasing the burden of proof raises further questions on the compatibility of the ideas of equality inherent in the risk-utility regime with the premise that product liability is there to protect the weaker party in a dispute about an accident caused by an unsafe product. Scholarly agreement on the specific issue of the influence of information on the liability of the producer is therefore not to be expected before theorists have come up with a regime that combines the emancipatory spirit of product liability law with the benefits of an aggregate point of view.

Competing Interests

The author has no competing interests to declare.

[93] Even though it is unclear if product liability actually prevents accidents (Polinsky & Shavell, ibid. pp. 1437–1492).

[94] Others warn for the risks of overwarning too: D. Van De Gehuchte, *Productaansprakelijkheid in België* (2000), p. 66; Hodges, supra note 8, p. 116; L. Simont & M. Von Kuegelgen, 'Belgium', in P. Kelly & R. Attree (eds.), *European Product Liability* (1992), p. 71. Discussing the *Sanofi Pasteur* case (*Sanofi Pasteur* supra, note 84) Fagnart remarks that holding a producer of vaccines liable for side effects which are not scientifically proven incentivizes producers to add them to the safety notice, which only adds to the (unwarranted) hostility towards vaccines (J.-L. Fagnart, 'L'imaginaire et son régime probatoire. Commentaire de l'arrêt du 21 juin 2017 de la Cour de Justice européenne', (2017) *Revue Générale des Assurances et des Responsabilités*, nr. 15412, p. 7 f°).

[95] R. Posner, *Economic Analysis of Law* (2014), p. 32.

[96] Similarly, A. Ripstein, *Private Wrongs* (2016), p. 5.

How to cite this article: Thomas Verheyen, 'Modern Theories of Product Warnings and European Product Liability Law' (2019) 15(1) Utrecht Law Review pp. 44–56. DOI: https://doi.org/10.36633/ulr.541

Published: 13 December 2019

Utrecht Law Review is a peer-reviewed open access journal published by Utrecht University School of Law.

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